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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,077	02/19/2004	Sylvic Demay	069208.0118	4531

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BAKER BOTTS, LLP
910 LOUISIANA
HOUSTON, TX 77002-4995

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,077	DEMAY ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14, 16 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14, 16 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2006 has been entered.

Notice of Amendment

2. In response to the amendment filed on 10/19/2006, amended claim(s) 1, 20, and 23, canceled claim(s) 10-13, 15, and 17-19, and new claim(s) 27-28 is/are acknowledged. The current rejections of the claim(s) 1-9, 14, 16, and 20-26 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

4. The abstract of the disclosure is objected to because of excessive length (i.e. greater than 150 words). Correction is required. See MPEP § 608.01(b).

Claim Objections

5. Claims 6, 21, and 25 are objected to because of the following informalities: the positive recitation of “a hollow guide” appears to duplicate the positively recited “a guide” structure claimed in claims 1, 20, and 25, respectively and/or is ambiguous.

Appropriate correction is required.

6. Claims 7, 22, and 26 are objected to because of the following informalities: the positive recitation of “a first and second set of projections” appears to duplicate the positively recited “a first set of projections... and a second set of projections” structure claimed in claims 1, 20, and 25, respectively and/or is ambiguous. Appropriate

correction is required.

7. Claim 8 is objected to because of the following informalities: the positive recitation of “at least one flexible projection” appears to duplicate the positively recited “a first and second set of projections” structure of claim 7 and furthermore appears to duplicate the positively recited “a first set of projections... and a second set of projections” structure claimed in claim 1 and/or is ambiguous. Appropriate correction is required.

8. Claim 9 is objected to because of the following informalities: the positive recitation of “the a first set of projections” appears to render the claim indefinite, is ambiguous, and/or a typographical error is present. Appropriate correction is required.

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9. Claims 16 and 23 are objected to because of the following informalities: the positive recitation of "the collection bag" appears to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.
10. Claims 16 and 23 are objected to because of the following informalities: the positive recitation of "the collection bag" appears to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.
11. Claim 28 is objected to because of the following informalities: the positive recitation of "the needle" appears to lack antecedent basis and may render the claim indefinite. The Examiner notes the positively recited "the needle" structure is not present in independent claim 1, but alternatively in dependent claim 6. Appropriate correction is required.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-9, 14, 20-22, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathias et al (US 6,387,086) in view of Eichhorn et al (US 4,320,769) as broadly as structurally claimed.

- For claims 1, 2, and 20, Mathias et al discloses a bag system for collecting a biological fluid (e.g. blood) (see Abstract) initially void of biological fluid, comprising:
 - a collection device (10);
 - a fluid collection bag (16) in fluid communication with the collection device;
 - a sampling device (18) in fluid communication with the collection device, the sampling device including:
 - at least one sampling receptacle (70); and
 - a transfer device (68 as best seen in Figure 4D) having an associating device (the inside faces of element 68);
 - wherein the associating device includes a guide (98 and 100) having a set of longitudinally disposed deformable projections (the inside face of elements 98 and 100).
- For claim 3, Mathias et al discloses a system, further comprising: a first tube (15) between the collection device and the fluid collection bag and a second tube (62) between the collection device and the sampling device.

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- For claim 4, Mathias et al discloses a system, wherein the sampling device (18) further comprises a sampling bag (42) connected to the downstream end of the second tube.
- For claims 5 and 21, Mathias et al discloses a system, wherein the receptacle (70) has a body having a first diameter and further comprises a closure element (84) having a second diameter greater than the first diameter.
- For claims 6 and 21, Mathias et al discloses a system, wherein the transfer device further comprises: said guide (68) open at a front part and a hollow needle (74 & Column 6, lines 52-55) in fluid communication with the bag system.
- For claim 14, Mathias et al discloses a system, wherein the guide further comprises a cap having a tamper-evident element (17).

15. Mathias et al discloses the claimed invention except for explicitly disclosing the guide having two sets of deformable projections distributed longitudinally on an internal face of the guide wherein a first set of the projections disposed near the needle is breakable under deformation. Eichhorn et al teaches a guide (10 and 100) having two sets of deformable projections (12 and 102) distributed longitudinally on an internal face of the guide wherein a first set of the projections disposed near the needle is capable of breaking under deformation and wherein a second set of projections is located near a front region of the guide (as best seen in Figures 2 and 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fluid collection system as taught by Mathias et al, with the projections as taught by

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Eichhorn et al for the purpose of increasing the efficacy of a bodily fluid withdrawal system to function safely with respect to the patient and caretaker.

16. Claims 16 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathias et al in view of Eichhorn et al as applied to claims 1-9, 14, 20-22, and 27-28 above, and further in view of Ishida (US 5,125,920).

17. Mathias et al in view of Eichhorn et al discloses the claimed invention, as aforementioned, except for explicitly disclosing a collection bag and receptacle with at least two identification tags. Ishida teaches a identification tags disposed on the collection bag (25) and disposed on the receptacle (26 and 27 & Column 5, lines 16-23), wherein the tags allows the establishment, after their dissociation, that both the collection bag and receptacle originated from the same bag system (Column 5, lines 37-39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fluid collection system as taught by Mathias et al in view of Eichhorn et al, with identification as taught by Ishida for the purpose of increasing the efficacy of a bodily fluid withdrawal system to function safely with respect to the patient and caretaker.

Response to Arguments

18. Applicant's arguments with respect to claims 1-9, 14, 16, and 20-28 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

JH



Max F. Hindenburg
Supervisor